

PATENT COOPERATION TREATY

PCT



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference OP04-1082	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/KR2004/002757	International filing date(<i>day/month/year</i>) 29 OCTOBER 2004 (29.10.2004)	Priority date (<i>day/month/year</i>) 31 OCTOBER 2003 (31.10.2003)	
International Patent Classification (IPC) or national classification and IPC C07K 19/00(2006.01)i			
Applicant KIM, Tae-Yoon et al			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: <ul style="list-style-type: none"> a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>4</u> sheets, as follows: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 507 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand 29 MARCH 2005 (29.03.2005)	Date of completion of this report 13 JANUARY 2006 (13.01.2006)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer PARK, JEONG UNG  Telephone No. 82-42-481-8159

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/002757

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☒ This report is based on translations from the original language into the following language English which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☒ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
pages 1-51 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____
- ☒ the claims:
pages 53 as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* 52, 54-56 received by this Authority on 31/08/2005
pages* _____ received by this Authority on _____
- ☒ the drawings:
pages 1/27-27/27 as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____
- ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☒ the claims, Nos. 16-19
- ☐ the drawings, sheets _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 7,14

because:

☒ the said international application, or the said claims Nos. 7,14
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 7, 14 relate to a method of treatment of the human or animal body and according to Art.34(4)(a)(i) and Rule 67.1(iv) PCT, the IPEA is not required to carry out an international preliminary examination on this claims.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the
Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with
the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/002757

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6, 8-13, 15-19	YES
	Claims		NO
Inventive step (IS)	Claims	1-6, 8-13, 15-19	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-6, 8-13, 15-19	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The present invention relates to extracellular superoxide dismutase (EC-SOD) fusion proteins and compositions comprising such fusion proteins. The fusion proteins can be used in a variety of applications, including the design of anti-aging cosmetics or the treatment of skin diseases.

The following documents have been considered for the purpose of this report:

D1: Park, J.S., et al., Mol. Cells, 13(2): 202-208 (Nov. 09, 2001)

D2: US 5366729 (Nov. 22, 1994)

1. Novelty

D1 describes the enhanced penetration efficiency of Cu,Zn-superoxide dismutase (Cu,Zn-SOD) fused with a gene fragment that encodes the 9 amino acids Tat protein transduction domain (RKRRRQRRR) of HIV-1 and lysine rich peptide (KKKKKKKKK) in a bacterial expression vector in order to produce a genetic in-frame Tat-SOD and 9Lys-SOD fusion protein. D2 relates to EC-SOD variants and the use thereof for the purpose of therapeutic treatment. The extracellular superoxide dismutase (EC-SOD) and the extracellular superoxide dismutase (EC-SOD) fused with a gene fragment that encodes the Tat protein transduction domain of HIV-1 and lysine rich peptide are not disclosed in any of the prior art. Therefore, the subject-matter of claims 1-6, 8-13, 15-19 is considered to be novel under PCT Article 33(2).

2. Inventive Step

The present invention provides a extracellular superoxide dismutase (EC-SOD), fusion proteins thereof, and compositions comprising such fusion proteins. D1 and D2 disclose the Cu,Zn-SOD and fusion proteins thereof as well as the use for therapeutic treatment of Cu,Zn-SOD and EC SOD variants. However, the present invention shows a difference in the type of SOD as compared with D1 and D2. The objects of D1 and D2 are different from that of the present invention in that D1 and D2 are to provide a different SOD type. The prior arts do not teach or suggest the expression of EC-SOD mRNA in dermal layer to protect the dermal connective tissue from reactive oxygen species. The special effect that comes with the construction of the present invention is recognized to be unforeseen from prior arts. Therefore, the subject-matter of claims 1-6, 8-13, 15-19 is considered to involve an inventive step under PCT Article 33(3).

3. Industrial Applicability

The subject-matter of claims 1-6, 8-13, 15-19 is considered to be industrially applicable under PCT Article 33(4).